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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,287	06/19/2008	Hans Michael Burger	33617-US-PCT	8865

1095 7590 11/09/2011

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 101/2  
EAST HANOVER, NJ 07936-1080

EXAMINER
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SACKEY, EBENEZER O

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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11/09/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,287	<b>Applicant(s)</b> BURGER ET AL.	
	<b>Examiner</b> EBENEZER O. SACKY	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 8-10 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 8-10 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### **Status of the Claims**

Claims 1-7 have been cancelled.

New claims 8-10 have been presented.

New claims 8-10 are rejected.

This is in response to applicant's amendment filed on 08/10/11.

The rejection of claims 1, 3 and 5-7 under 35 U.S.C. 112, second paragraph has been withdrawn in view of the cancellation of the claims. However, a new rejection under 35 U.S.C. 112, second paragraph follows.

### ***Claim Objections***

New claim 9 is objected to because the claim is dependent on cancelled claim 1. Claim 9 is being interpreted as being dependent on claim 8.

### ***Claim Rejections - 35 U.S.C. § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmermann et al., (WO 99/03854) in view of Ekwuribe et al., (U.S. Patent number 6,479,692)('692') for the reasons set forth in the previous office action mailed on 05/11/11.

### ***Response to Amendment***

Applicant's arguments filed 08/10/11 have been fully considered but they are not persuasive. Applicants argue that one of ordinary skill in the art would not expect the presently claimed salts to have solubility above 50 mg/ml and thus, the data provided in the specification demonstrates the patentability of the present claims. Contrary to applicants assertion, as previously stated in previous office action, Ekwuribe et al., clearly states that salts such as claimed herein i.e., tartrate, succinate and malonate are salts that retain their biological desired activities of the parent compounds (drugs).

Applicants next argue that Example 23 demonstrates the patentability of the claimed salts and that the combined disclosure of the references would not lead the skilled artisan to the current invention. Contrary to applicant's arguments, it is well known in the art that certain salts are preferred in pharmaceutical formulations. Note there is no Example 8 (alluded to) in Example 23. Thus, the entire data becomes

questionable. It is not like applicants have provided any strong evidence to show that the claimed salts provided rare, favorable significant activities, characteristics or properties that is absent in the parent drug or compound. Thus, applicants need to show the degree of kind of rarity, if any possessed by the current salts and needs to show that such rarity is not a predicted property or activity. The asserted patentability is not convincing. Moreover, there are various salts approved by the FDA on the market. Note *Pfizer, Inc. v. Apotex, Inc.* 82 U.S.P.Q. 2d. 1321 (Fed. Cir. 2007). Additionally, Berge (applied here for rebuttal) review article lists the most often used FDA salts on the market as of 1974 which include the tartrate salt in the top 5 for choice of acid addition salts.

Chaudary (also applied here for rebuttal) describes D-tartrate as a stable salt for bulk preparation and handling. See page 1, left column.

Andrews (also applied here for rebuttal) describes the use of tartrate salt as the preferred salt. See column 5, lines 25-29.

Thus, for the reasons of record, new claims 8-10 are again rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EBENEZER O. SACKY whose telephone number is (571)272-0704. The examiner can normally be reached on 7.30-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/EBENEZER O SACKY/  
Examiner, Art Unit 1624**

**/JAMES O. WILSON/  
Supervisory Patent Examiner, Art Unit 1624**